Food and Drug Administration, HHS

soluble extracts which contain high melting waxes (melting point greater than 170 °F), it may be necessary to dilute the heptane solution further so that a 50-milliliter aliquot will contain only 0.1–0.2 gram of the chloroform-soluble extract residue.)

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter, except where the copolymers are restricted to use in contact with food only of the type identified in paragraph (c), table 1 under Category VIII.

[42 FR 14554, Mar. 15, 1977]

N-Cyclohexyl-p-toluene sulfonamide.. 2,5-Di-tert-butyl hydroquinone.

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §176.170, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§176.180 Components of paper and paperboard in contact with dry food.

The substances listed in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food of the type identified in §176.170(c), table 1, under Type VIII, subject to the provisions of this section.

- (a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.
- (b) The substances permitted to be used include the following:
- (1) Substances that by §176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.
- (2) Substances identified in the following list:

	7
List of substances	Limitations
Acrylamide polymer with sodium 2-acrylamido-2-methylpropane-sulfonate (CAS Reg. No. 38193–60–1). (2-Alkenyl) succinic anhydrides in which the alkenyl groups are	For use at a level not to exceed 0.015 weight percent of dry fiber.
derived from olefins which contain not less than 78 percent	
C_{30} and higher groups (CAS Reg. No. 70983–55–0) 4-[2-[2-(2-Alkoxy(C_{12} - C_{15}) ethoxy) ethoxy]ethyl]disodium sulfosuccinate.	For use as a polymerization emulsifier and latex emulsion stated bilizer at levels not to exceed 5 percent by weight of total
Succinate.	emulsion solids.
Alkyl mono- and disulfonic acids, sodium salts (produced from n -alkanes in the range of C_{10} - C_{18} with not less than 50 percent C_{14} - C_{16})	
Aluminum and calcium salts of FD & C dyes on a substrate of alumina.	Colorant.
Ammonium nitrate	
Amylose	
Barium metaborate	For use as preservative in coatings and sizings.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634–33–5)	For use only as a preservative in paper coating composition and limited to use at a level not to exceed 0.02 mg/in (0.0031 mg/cm²) of finished paper and paperboard.
N,N'-Bis(hydroxyethyl)lauramide.	
Bis(trichloromethyl) sulfone C.A. Registry No. 3064-70-8	For use only as a preservative in coatings.
Borax	For use as preservative in coatings.
Boric acid	Do.
Butanedioic acid, sulfo-1,4-di-(C ₉ -C ₁₁ alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093–88–9])	For use as a surface active agent in package coating inks a levels not to exceed 3 percent by weight of the coating ink.
sec-Butyl alcohol.	
Butyl benzyl phthalate Candelilla wax	
Carbon tetrachloride	
Castor oil, polyoxyethylated (42 moles ethylene oxide)	
Cationic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyl-trimethylammonium chloride).	For use only as a coating adhesive, pigment structuring ager and fiber retention aid.
Cationic soy protein (soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethyl-ammonium chloride).	For use only as a coating adhesive, pigment structuring ager and fiber retention aid.
Chloral hydrate	Polymerization reaction-control agent.

21 CFR Ch. I (4-1-12 Edition)

List of substances	Limitations
Diethanolamine Diethylene glycol dibenzoate (CAS Reg. No. 120–55–8)	For use only as a plasticizer in polymeric substances.
Diethylene glycol monobutyl ether Diethylene glycol monoethyl ether	
Diethylenetriamine N,N-Diisopropanolamide of tallow fatty acids	
N-[(dimethylamino)methyl]acrylamide polymer with acrylamide and styrene	
N,N-Dioleoylethylenediamine, N,N-dilinoeoyl-ethylenediamine,	
and N-oleoyl-N-linoleoyl-ethylenediamine mixture produced	
when tall oil fatty acids are made to react with ethylene- diamine such that the finished mixture has a melting point of	
212°-228 °F, as determined by ASTM method D127-60, and an acid value of 10 maximum. ASTM Method D127-60	
"Standard Method of Test for Melting Point of Petrolatum	
and Microcrystalline Wax" (Revised 1960) is incorporated by reference. Copies are available from University Microfilms	
International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or	
available for inspection at the National Archives and Records Administration (NARA). For information on the availability of	
this material at NARA, call 202-741-6030, or go to: http://	
www.archives.gov/federal_register/ code of federal regulations/ibr locations.html	
Diphenylamine	
Dipropylene glycol dibenzoate (CAS Reg. No. 27138–31–4) Disodium N-octadecylsulfosuccinamate	For use only as plasticizer in polymeric substances.
tert-Dodecyl thioether of polyethylene glycol	
Erucamide (erucylamide) Ethanedial, polymer with tetrahydro-4-hydroxy-5-methyl-	
2(1 <i>H</i>)pyrimidinone, propoxylated Ethylene oxide	Eumigent in citing
Ethylene oxide adduct of mono-(2-ethylhexyl) o-phosphate	Fumigant in sizing.
Fatty acid (C_{12} - C_{18}) diethanolamide Fish oil fatty acids, hydrogenated, potassium salt	
Formaldehyde	
Glyceryl monocaprate Glyceryl tribenzoate (CAS Reg. No. 614–33–5)	For use only as a plasticizer in polymeric coatings.
Glyoxal	
Glyoxal-urea-formaldehyde condensate (CAS Reg. No. 27013— 01–0) formed by reaction in the molar ratio of approximately	For use as an insolubilizer for starch in coatings.
47:33:15, respectively. The reaction product has a number	
average molecular weight of 278±14 as determined by a suitable method.	
Glyoxal-urea polymer (CAS Reg. No. 53037-34-6)	For use as an insolubilizer for starch. Polymerization crosslinking agent for protein, including casein
	As neutralizing agent with myristochromic chloride complex and stearato-chromic chloride complex.
Hexylene glycol (2-methyl-2,4-pentanediol) Hydroabietyl alcohol	
5-Hydroxymethoxymethyl-1-aza-3,7-dioxabicyclo[3.3.0] octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-	For use only as an antibacterial preservative.
hydroxypoly-[methyleneoxy]methyl-1-aza-3,7-	
dioxabicyclo[3.3.0] octane mixture. Imidazolium compounds, 2–(C ₁₇ and C ₁₇ -unsaturated alkyl)-1–	For use only at levels not to exceed 0.5 percent by weight o
[2-(C ₁₈ and C ₁₈ -unsaturated amido)ethyl]-4,5-dihydro-1-	the dry paper and paperboard.
methyl, methyl sulfates (CAS Reg. No. 72749–55–4) Isopropanolamine hydrochloride	
Isopropyl <i>m</i> - and <i>p</i> -cresol (thymol derived)	
Itaconic acid Maleic anhydride-diisobutylene copolymer, ammonium or so-	
dium salt	Basic polymer.
Melamine-formaldehyde modified with: Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl).	basic polymer.
Diethylenetriamine. Imino-bis-butylamine.	
Imino-bis-ethyleneimine.	
Imino-bis-propylamine. Polyamines made by reacting ethylenediamine or	
trimethylenediamine with dichloroethane or dichloropropane.	
Sulfanilic acid. Tetraethylenepentamine.	
Triethylenetetramine.	
Methyl alcohol	I

List of substances	Limitations
Methyl napthalene sulfonic acid-formaldehyde condensate, so-dium salt	
Methylated poly(<i>N</i> -1,2-dihydroxyethylene-1,3-imidazolidin-2-one).	For use only only as an in solubilizer for starch.
Modified polyacrylamide resulting from an epichlorohydrin addition to a condensate of formaldehyde-dicyandiamide-diethylene triamine and which product is then reacted with polyacrylamide and urea to produce a resin having a nitrogen content of 5.6 to 6.3 percent and having a minimum viscosity in 56 percent-by-weight aqueous solution of 200 centipoises at 25 °C, as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 60 r.p.m. (or equivalent method).	For use only as a dry strength and pigment retention aid ager employed prior to the sheetforming operation in the manufacture of paper and paperboard and used at a level not texceed 1 percent by weight of dry fibers.
Mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of C ₁₅ -C ₂₁ groups.	For use only as an emulsifier.
Monoglyceride citrate	
Myristo chromic chloride complex Napthalene sulfonic acid-formaldehyde condensate, sodium salt	
Nickel	
β-Nitrostyrene Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea (CAS Reg. No. 68412–14-6), and the acetate salts thereof (CAS Reg. No. 68784–21-4), which may be emulsified with ethoxylated tallow alkyl amines (CAS Reg. No. 61791–26–2).	Basic polymer. For use prior to sheet forming at levels not to exceed 1: pounds per ton of paper.
α-cis-9-Octadecenyl-omega-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages not less than 20 moles	
α -(p-Nonylphenyl)-omega-hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles	
Oleic acid reacted with N -alkyl-(C_{16} - C_{18}) trimethylenediamine Oxidized soy isolate having 50 to 70 percent of its cystine residues oxidized to cysteic acid.	For use as a binder adhesive component of coatings.
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with the identity prescribed in §176.170(b)(2).	For use as modifiers at levels up to 30 weight-percent of th solids content of wax-polymer blend coatings.
Petroleum hydrocarbon resins (produced by the catalytic po- lymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked pe- troleum stocks)	
Petroleum hydrocarbons, light and odorless	
o-Phthalic acid modified hydrolyzed soy protein isolate	
Pine oil Poly(2-aminoethyl acrylate nitrate-co-2-hydroxypropyl acrylate) complying with the identity described in §176.170(a)	
Polyamide-epichloro hydrin modified resins resulting from the reaction of the initial caprolactam-itaconic acid product with diethylenetrianine and then condensing this prepolymer with epichlorohydrin to form a cationic resin having a nitrogen content of 11–15 percent and chlorine level of 20–23 percent	
on a dry basis	
Polyamide-ethyleneimine-epichlorohydrin resin is prepared by reacting equimolar amounts of adipic acid and three amines (21 mole percent of 1,2-ethanediamine, 51 mole percent of N-(2-aminoethyl)-1,3-propanediamine, and 28 mole percent of N, N'-1,2-ethanediylbis(1,3-propanediamine)) to form a basic polyamidoamine which is modified by reaction with	
ethyleneimine (5.5:1.0 ethyleneimine:polyamidoamine). The modified polyamidoamine is reacted with a crosslinking agent made by condensing approximately 34 ethylene glycol units with (chloromethyl)oxirane, followed by pH adjustment with formic acid or sulfuric acid to provide a finished product	
as a formate (CAS Reg. No. 114133-44-7) or a sulfate (CAS Reg. No. 167678-43-5), having a weight-average molecular weight of 1,300,000 and a number-average molecular weight of 16,000	

21 CFR Ch. I (4-1-12 Edition)

List of substances	Limitations
Polyamide-ethyleneimine-epichlorohydrin resin (CAS Reg. No. 115340–77–7), prepared by reacting equimolar amounts of adipic acid and <i>N</i> -(2-aminoethyl)-1,2-ethanediamine to form a basic polyamidoamine which is modified by reaction with ethyleneimine, and further reacted with formic acid and (chloromethyl)oxirane-α-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl).	
Polybutene, hydrogenated; complying with the identity pre- scribed under § 178.3740(b) of this chapter Poly [2-(diethylamino) ethyl methacrylate] phosphate Polyethylene glycol (200) dilaurate	
Polyethylene glycol monoisotridecyl ether sulfate, sodium salt (CAS Reg. No. 150413–26–6).	For use only as a surfactant at levels not to exceed 3 percent in latex formulations used in pigment binders for paper and paperboard.
Polymers: Homopolymers and copolymers of the following monomers: Acrylamide.	Basic polymer.
Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters. Acrylonitrile. Butadiene. Crotonic acid. Cyclol acrylate.	
Decyl acrylate. Diallyl fumarate. Diallyl maleate. Diallyl phthalate. Dibulyl fumarate.	
Dibutyl itaconate. Dibutyl maleate. Di(2-ethylhexyl) maleate. Dioctyl fumarate.	
Dioctyl maleate. Divinylbenzene. Ethylene. 2-Ethylhexyl acrylate. Fumaric acid.	
Glycidyl methacrylate. 2-Hydroxyethyl acrylate. <i>N</i> -(Hydroxymethyl) acrylamide. Isobutyl acrylate.	
Isobutylene. Isoprene. Itaconic acid. Maleic anhydride and its methyl or butyl esters. Methacrylic acid and its methyl, ethyl, butyl, or propyl esters.	
Methylstyrene. Mono(2-ethylhexyl) maleate. Monoethyl maleate. 5-Norbornene-2,3-dicarboxylic acid, mono- <i>n</i> -butyl ester.	
Styrene. Vinyl acetate. Vinyl butyrate. Vinyl chloride.	
Vinyl crotonate. Vinyl hexoate. Vinylidene chloride. Vinyl pelargonate.	
Vinyl propionate. Vinyl pyrrolidone. Vinyl sterate. Vinyl sulfonic acid.	
propionaldehyde (CAS Reg. No. 106569–82–8). Polyoxyethylene (minimum 12 moles) ester of tall oil (30%–40% rosin acids). Polyoxypropylene-polyoxyethylene glycol (minimum molecular	For use only as a starch and protein reactant in paper and pa- perboard coatings.
weight 1,900) Polyvinyl alcohol Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20–0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of K-Ti ₄ O ₉ and K-Ti	
60 ₁₃	

Food and Drug Administration, HHS

List of substances	Limitations
Sodium diisobutylphenoxy diethoxyethyl sulfonate Sodium diisobutylphenoxy monoethoxy ethylsulfonate Sodium n-dodecylpolyethoxy (50 moles) sulfate Sodium isododecylphenoxypolyethoxy (40 moles) sulfate Sodium N-methyl-N-oleyl taurate Sodium methyl siliconate Sodium nitrite Sodium polyacrylate Sodium bis-tridecylsulfosuccinate Sodium xylene sulfonate	
Stearato chromic chloride complex	
Styrene-allyl alcohol copolymers Styrene-methacrylic acid copolymer, potassium salt	
Tetraethylenepentamine	Polymerization cross-linking agent.
hydroxypoly (oxyethylene) where nonyl group is a propylene trimer isomer	
Tetrasodium <i>N</i> -(1,2-dicarboxyethyl)- <i>N</i> -octadecyl sulfosuccinamate	
Toluene Triethanolamine	
Triethylenetetramine	Polymerization cross-linking agent.
Diphenylamine. N.N'-Distearoylethylenediamine. Ethylenediamine. Guanidine.	
Imino-bis-butylamine. Imino-bis-ethylamine. Imino-bis-propylamine.	
N-Oleoyl-N-stéaroylethylenediamine. Polyamines made by reacting ethylenediamine or trethylenediamine with dichloroethane or dichloropropane. Tetraethylenepentamine. Triethylenetetramine.	
Xylene Xylene sulfonic acid-formaldehyde condensate, sodium salt Zinc stearate	

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting \$176.180, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

$\$\,176.200$ Defoaming agents used in coatings.

The defoaming agents described in this section may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

- (a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.
- (b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or technical effect in the defoaming agents or any limitation further provided.